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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,927	04/09/2007	Axel Niendorf	5151-21PUS	4186

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EXAMINER

STRZELECKA, TERESA E

ART UNIT	PAPER NUMBER
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1637

MAIL DATE	DELIVERY MODE
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12/03/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/590,927	Applicant(s) NIENDORF ET AL.	
	Examiner TERESA E. STRZELECKA	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 24-60 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. This additional Election/Restriction requirement is provided in response to Applicant's response filed September 25, 2008. The reasoning for issuing the election requirement is explained in further detail, as is the requirement of how the species need to be elected.
2. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Species of tissue section preparation

- A) sections are prepared when the tissue sample is fresh (claims 29, 30),
- B) tissue sample is frozen (claims 31, 32),
- C) the tissue sample is mounted on a slide and frozen immediately after the tissue sample is removed from a patient, and the sections are prepared from the frozen tissue sample with a microtome (claims 33-35).

Species of non-morphological analytical testing

- D) non-morphological analytical testing comprises detecting bio-molecules or determining a biophysical characteristic of the at least another one of the prepared sections, the bio-molecules including genomic DNA, cDNA, mRNA, epigenomic methylation pattern, proteins, viral or bacterial nucleic acids, infectious prions, nucleic acids or proteins of pathogenic parasites (claims 40, 41),

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E) non-morphological analytical testing comprises determination of a quantity which makes it possible to determine at least one of a fraction of diseased tissue and a fraction of another tissue component in the tissue sample, and the at least one of a fraction of diseased tissue and a fraction of another tissue component so determined is used quantitatively as a basis of evaluation of the result of the non-morphological analytical testing (claims 42, 43).

Species of treatment of biological molecules

F) the bio-molecules to be detected by the non-morphological analytical testing are subjected to a labeling step (claims 46, 48),

G) the nucleic acids to be detected by the non-morphological analytical testing are subjected to an amplification step (claims 47, 49).

Species of histological/cytological examination

H) comprises at least one staining step (claims 50, 51),

I) comprises at least one of an immunohistochemical step and an in situ hybridization step (claims 52, 53).

Species of using the method

J) to develop a tumor data bank (claims 55, 56),

K) to develop an individualized cancer therapy (claims 57, 58),

L) to adjust patient's individualized cancer therapy (claims 59, 60).

Applicant is required, in reply to this action, to elect a single species from each of the sets of species, i.e. a single species from species A-C, a single species from species D or E, a single species from species F or G, a single species from species H or I and a single species from species J-L (a total of 5 species to be elected) to which the claims shall be restricted if no generic

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claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: 24 and 25.

3. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Erlander et al. (US 2003/0186248; cited in the IDS and in the previous requirement) teach the methods of claims 24 and 25 including some of the species (page 2, [0015]-[0017]; page 3, [0019]-[0024]; page 4, [0025]-[0028]; page 6, [0043]; page 7, [0064]-[0065]; page 10, [0099]-[0100]; page 11, [0101]; page 12, [0120]; page 13; page 14, [0133]-[0134]). Therefore the species lack a unifying special technical feature.

Specifically, Erlander et al. teach a method comprising:

taking a sample from the tissue sample (page 3, [0020];

subjecting at least one portion of the sample to a histological/cytological examination (page 3, [0023]); and

subjecting at least another portion of the sample to a non-morphological analytical testing (page 3, [0024]; page 4, [0028]),

wherein in the histological/cytological examination, at least one of a quantitative fraction of diseased tissue or cells and another morphological aspect of the at least one portion of the

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sample is determined by an image processing system (page 4, [0025]; page 6, [0039]; page 7, [0064]), and

wherein the determined at least one of a quantitative fraction of diseased tissue or cells and another morphological aspect is used as a reference quantity on which evaluation of a result of the non-morphological analytical testing is based (page 3, [0022] and [0024]).

Therefore, the claims do not contain a unifying special technical feature, since they do not represent a contribution over the prior art, as defined by PCT RULE 13.2:

§ 13.2 Circumstances in Which the Requirement of Unity of Invention Is to Be Considered Fulfilled

Where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in **Rule 13.1** shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

4. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

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application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TERESA E. STRZELECKA whose telephone number is (571)272-0789. The examiner can normally be reached on M-F (8:30-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Teresa E Strzelecka
Primary Examiner
Art Unit 1637

/Teresa E Strzelecka/
Primary Examiner, Art Unit 1637
November 28, 2008

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